# BERKLEY AND JENSEN ASPIRIN- aspirin tablet, film coated BJWC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### **BJWC Aspirin Drug Facts**

#### Active ingredient (in each tablet)

Aspirin 325 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

## **Purposes**

Pain reliever/fever reducer

#### Uses

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

#### Do not use

if you have ever had an allergic reaction to any other pain reliever/fever reducer

#### Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

#### Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- diabetes
- gout
- arthritis

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition

#### If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### **Directions**

• drink a full glass of water with each dose

- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

#### Other information

• store at 20°-25°C (68°-77°F)

## **Inactive ingredients**

corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

#### Questions or comments?

1-800-934-1204

# **Principal Display Panel**

Compare to the active ingredient in Bayer® Aspirin

**ASPIRIN** 

PAIN RELIEVER/FEVER REDUCER (NSAID)

FOR ADULTS

SAFE PAIN RELIEF PLUS LIFESAVING BENEFITS

TALK TO YOUR DOCTOR OR OTHER HEALTHCARE PROVIDER BEFORE USING THIS PRODUCT FOR YOUR HEART.

**GLUTEN FREE** 

325 mg EACH

**500 COATED TABLETS** 

325 mg EACH

**ACTUAL SIZE** 





Drug FeatSt (Continued)

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### **BERKLEY AND JENSEN ASPIRIN**

aspirin tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68391-416

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength
I	ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

# Inactive Ingredients Ingredient Name Strength STARCH, CORN (UNII: 08232NY3SJ) DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: 07TSZ97GEP) HYPROMELLOSES (UNII: 3NXW29V3WO) TALC (UNII: 7SEV7J4R1U) TRIACETIN (UNII: XHX3C3X673)

<b>Product Characteristics</b>	ict Characteristics					
Color	WHITE	Score	no score			
Shape	ROUND	Size	14mm			

Flavor		Imprint Code	4	Aspirin;L				
Contains								
Packaging								
# Item Code	Package Desc	ription	Marketing Start Date	Marketing End Date				
1 NDC:68391-416-90	500 in 1 BOTTLE; Type 0: Not a	BOTTLE; Type 0: Not a Combination Product						
Marketing Information								
Marketing Categor	y Application Number or	Monograph Citation	Marketing Start Date	e Marketing End Date				
OTC monograph not fin	al part343		07/23/2008					

# **Labeler -** BJWC (159082692)

Revised: 8/2018 BJWC